

**12. Report on the Practical Use of a New Device (Y2)****Showa 60-31706**

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54. Name of Idea              CERAMIC SPINAL CORD PROSTHETIC MATERIAL

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**57. Area covered by the Request to Register a Practical Use of a New Device**

1. Made of ceramic 5, which is formed in similar shape and measurement to the spinal column intervertebral disc 7 and/or vertebral body 100; a ceramic spinal column prosthetic material that resembles a honeycomb, composed of many pillar-like holes 4 with effective openings of diameter 0.2 mm or more to allow for increase, entry and development of this bone structure 7 and/or 100 with respect to that which is inside the top and bottom surfaces 1 and 2 that come in contact with this spinal column bone structure 7 and/or 100.

2. Material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned pillar-like holes 4 are the blind holes 41 that extend and stop at the inside of each of the top and bottom surfaces 1 and 2 of the above mentioned ceramic 5.
3. Part material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned pillar-like holes 4 are the penetrating holes 42 that pass through the above mentioned ceramic 5 in the lengthwise direction.
4. Part material that is mentioned in paragraph 1 of the "Request to Register a Practical Use of a New Device," where the above mentioned ceramic 5 is an alumina linked crystal, alumina ceramic body, or mullite ceramic body.

#### **Detailed Explanation**

This idea involves a ceramic spinal column prosthetic material that is used in treatment in plastic surgery, and relates to spinal column prosthetic material that is made to insert in between the spinal column structure for spinal column plastic surgery.

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With the developments in bio-engineering, treatment involving implants of material (screw pins, blades, etc.) into bone structures have become more common in the areas of dentistry and plastic surgery, taking the place of metal artificial prosthetic material; and in these cases, the applicant has provided various inventions that use ceramic, such as alumina ceramic, that, as implant material, adapt well with bone structures and are not harmful in any way. For instance, there are structures like the ceramic bone implant part material that has many holes at the contact surface area that is indicated in (1976)-116809, where it is imbedded into the bone structure to repair the bone structure through the entry of newly created bone structure through the many air passages created on the front surface area that comes in contact with the bone structure.

However, these implant material for the bone have been for hard, solid structures, and in structures that have relatively little load; thus, to use these as they are, structurally and functionally, for complex and for prosthetic material for the spinal column that has high degree of load, has been deemed difficult from the point of view of strength. However, the spinal column supports body weight,

and when lifting or carrying things, there is significant load placed in the lengthwise direction of the spinal column, and at the same time, because there is constant twisting force applied with the movement of the body, there has been a problem, in terms of strength, in using this type of bone implant material that involves three-dimensional space as prosthetic material.

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For this reason, repair procedure for the spinal column has often been to insert into the patient artificial metal prosthetic material that is durable, or to remove the ileum which is of the same soft structure as the spinal column bone structure, and transplant this into the patient. However, when artificial metal prosthetic material is used, there is a problem with it not adapting biologically, and with harmful effects from corrosion within the body. Also, transplants using ileum requires time and labor with surgery, as well as cause the patient much pain and additional burden.

This idea takes into account the existing situation with the current spinal column prosthetic methods, and aims to provide an artificial prosthetic material that is superior in maintenance, has the strength to withstand sufficient load to the spinal column, has no harmful effects on the body, and adapts well to the body.

The following is a detailed explanation of the spinal column prosthetic material that is presented here.

The spinal column prosthetic material (SCPM) presented here adapts well to the body, is composed of ceramic material that has no harmful effects to the body, can be performed by simply inserting it into the appropriate section, and the point is that it is composed of many pillar-like holes in the lengthwise direction, like a honeycomb, with effective openings of diameter 0.2 mm or more to allow for increase, entry and development of this bone structure, with respect to the part that is inside the surface that comes in contact with the ceramic spinal column bone structure.

The effective openings mentioned here refers to that which is necessary for the bone structure that is adjacent to the top and bottom of the SCPM to increase and enter; it is also called the width diameter. Therefore, as long as this width diameter is of a value that allows for increase and entry of adjacent bone structures, the diameter of the pillar holes inside is not a problem.

Also, that the pillar-shaped holes have an effective opening diameter of 0.2 mm or more is a necessary requirement for the effectiveness of the SCPM, where when an adjacent bone structure enters inside the SCPM (the vertebral body that makes up the spinal column is soft compared to the harder ceramic, so the vertebral body bone structure inserts easily into the pillar-shaped spaces of the SCPM, and this fact has already been confirmed in medical experiments), and on the prosthetic area is formed compound structures due to the ceramic and bone structures that have entered and increased. Load on the spinal column in the vertical direction is significant, and there is enough strength to withstand the...

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...force that is put in a twisting direction, and furthermore to easily conduct prosthetics that has maintenance (fixed) strength. Also, with this ceramic, because the prosthetic spinal column in general does not hinder the function it originally has, it goes without saying that it is manufactured in the well known method of "pressure-grind baking" alumina or mullite-type ceramic, with the shape that corresponds to the prosthetic part (for instance, the cervical vertebrae, thoracic vertebrae, lumbar vertebrae, and the intervertebral discs of each). Next, several ideal implementation samples of SCPM will be given, with detailed explanations.

Diagram 1 shows that which is used, among the materials for spinal column prosthetics, for prosthetic intervertebral discs. And also following, in 7 is shown a section of an intervertebral disc that has been removed, and 7 is a healthy intervertebral disc that remains inside the body even after spinal column prosthetics.

Intervertebral disc 7 ... is each of the 100 vertebral bodies that form the spinal column ... and is a fibrous soft structure that communicates to each other. From the point of view of the entire spinal column, it functions as sort of a shock absorber.

This type of incidents where prosthetic intervertebral discs become necessary are caused when, for instance, it must be removed because of problems such as a ruptured disc, and these are times when SCPM becomes especially important.

For instance, as shown in Diagram 2, simply insert the SCPM that is formed into the appropriate shape into the reciprocal spaces of vertebral body 100, 100 that has removed the intervertebral disc 7; and when only one part of vertebral body 100, 100 is removed, the suitable shape of the SCPM should be chosen to suit the part that has been removed.

Thus, when the intervertebral disc 7 undergoes prosthetics, the adjacent bone structures 100, 100 goes into ceramic 5 through holes 41 provided at the top and bottom surfaces. The SCPM 50 forms a compound structure made of ceramic and the bone structures that increase and enter by means of the principles described above, combines strongly with the adjacent top and bottom vertebral body 100, 100, and becomes a new structure that makes up a vertebral body.

In this case, in place of the intervertebral disc 7 that is a soft structure with high contractibility, a harder ceramic 5 is being used, thus it is no longer possible to fulfill a shock absorber function mentioned above, which existed in a healthy intervertebral disc. This is the same in the transplant case of the ileum (a hard structure) also mentioned above.

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Thus, with respect to the bad effects on the body that existed at times, and poor adaptability to the living body when artificial metal prosthetic materials were used, the SCPM made from ceramic eliminates these problems; and with respect to transplanting the ileum as a means of prosthetics, there is no more need to go through the extraction surgery of the ileum that is troublesome, and a huge burden on the part of the patient. Therefore, it proves to be significantly beneficial in terms of surgery as well as physically.

Furthermore, SCPM can obviously be used for prosthetics that include those cases when the vertebral body itself is missing from the spinal column.

For instance, for prosthetics of missing areas in the spinal column, including the vertebral body, follow Diagram 3 and produce a ceramic in the shape of the desired part, and set screws 61 and 62 onto the top and bottom edges of surface 12 to which the adjacent bone structures 100, 100 are to be connected. If screws 61 and 62 are made so that they are threaded in opposite directions to one another, then screwing and securing onto the adjoining bone structure 100, 100 will be simple and sound, thus favorable.

Diagram 4 shows a prosthetic condition where the SCPM shown in Diagram 3 is put between vertebral body 100, 100.

Other ideal implementation samples of SCPM are shown in Diagrams 5, 6, 7, 8, and 9. Diagram 5 shows top and bottom surfaces 1 and 2 that combine with the bone structure, and instead of the blind hole in Diagram 1, there is ... a slot 42. Diagram 6 shows the top and bottom surfaces of SCPM shown in Diagram 1, ...with multiple rounded protrusions 3, making it easier to insert into the adjacent bone structure, and to have an intervertebral disc that has a stronger connection to the adjacent bone structure. Diagram 7 shows a prosthetic vertebral body with, ... instead of the screws 61 and 62 at the top and bottom edges in Diagram 3, having multiple rounded protrusions 63. Diagram 8 has penetrating holes 41 whose cross-sections are shaped like that of an orange. Diagram 9 shows that with the many passage holes 41. Needless to say, these additional methods...

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...can be applied as deemed necessary. Furthermore, if SCPM is formed to match the shape of the vertebral body part to undergo prosthetics, it is possible to perform prosthetics on various parts of the vertebral body, and especially when doing prosthetics on areas composed of the spinal column including joint areas, set an artificial joint that can freely move forward, preferably within 10°, to the middle range of the ceramic, as necessary.

As mentioned above, the SCPM is adaptable to the body structure more than the common metal prosthetics material, and the structure allows for application of the ceramic as spinal column prosthetic material that is not harmful to the body. It is effective in replacing the bone transplant since it involves simply inserting it into where spinal column prosthetics becomes necessary, and at the same time, it allows for entry, increase and development of the bone structure that is adjacent to the pillar-like holes that lies lengthwise. The ceramic and newly created bone structure form a compound structure that strongly connects to adjacent bone structures, so it maintains strong connection even under added load and lateral deviation force to the spinal column. It is an epoch-making progress in plastic surgery.

## **A Simple Explanation of the Diagrams**

Diagram 1(a) shows one implemented sample (for intervertebral disc) using SCPM, from a diagonal view. Diagram 1(b) shows a diagonal view with one portion cut out. Diagram 2 shows the condition of the SCPM in Diagram 1(a) when used in spinal column prosthetics. Diagram 3 shows another SCPM implementation samples (for the connection part of the intervertebral disc and the vertebral body), from a diagonal view. Diagram 4 shows the condition of the SCPM in Diagram 3 when used in spinal column prosthetics. Diagram 5(a) shows another SCPM implementation sample (for intervertebral disc), from a diagonal view. Diagram 5(b) shows a diagonal view with one portion cut out. Diagrams 6, 8, and 9 are for intervertebral discs, and Diagram 7 shows the implementation sample, diagonal view, of the SCPM, showing each of the connecting parts of the intervertebral discs and the vertebral body.

Explanation of symbols 1 ... top surface, 2 ... bottom surface, 3 ... protrusion, 4 ... pillar-shaped holes, 41 ... penetrating holes, 42 ... blind holes, 5 ... ceramic, 7 ... intervertebral disc, 100 ... vertebral body, 61, 62 ... thread for screw, 63 ... protrusion.

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